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ACRP-CRO ANALYTICS WHITE PAPER

APPLYING THE POWER OF PERFORMANCE ANALYTICS TO THE CHALLENGE OF IMPROVING CLINICAL RESEARCH

This white paper presents the findings of groundbreaking research by ACRP and CRO Analytics. This collaboration was the first effort to identify through predictive modeling what investigative sites believe is critical to the success of their efforts and how well their research partners are addressing those needs.

This investigative site assessment research is part of a larger 360º balanced scorecard application being developed by CRO Analytics with support from ACRP and other partners. To be successful, clinical trial improvement initiatives must take into account all stakeholders – patients, site, sponsors, and service providers.

We'd like to thank the sites and research partner participants that made this research possible. We appreciate your efforts and interest in helping establish this important new tool to improve clinical research.

Executive Summary

Clinical research performance analytics – the rigorous measurement of service quality through predictive modeling – provides clinical researchers with the ability to break the logjam in study performance by isolating and measuring the key drivers of clinical trial *service* quality. Those key drivers differ from the perspective of each primary stakeholder – patients, sites, sponsors, and CROs. Understand, measure, and address them and trials will be more efficient – shorter and less costly.

This new approach is critically needed. What we've been doing isn't working. Virtually every KPI for every sponsor, CRO, or trial is a measurement of time or quantity and not the underlying causes of that data. KPI's are a symptom not a diagnosis. Industry isn't collecting the data needed for a proper diagnosis. Such an analysis must be done from the perspective of a service because a trial is a service supported by processes and systems.

Contrary to popular perception, service quality can be rigorously measured. There's even a well-established validated instrument, ServQual, that over years of use has identified the key components and the percent to which each contributes to overall quality: Reliability, Responsiveness, Assurance, Empathy, and Tangibles.

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Our research examined what drives clinical trial performance from the site's perspective; and how well are site research partners performing on those drivers. What these findings show is that the meaningfulness or impact of communication and the protocol are the most significant predictors of a high quality clinical trial experience from the perspective of investigative sites along with the contracting process/budget, technology, and monitors. They also show that overall the industry is scoring "average" at best and with clear, consistent sponsor performance that is scored slightly higher than CROs.

But what is most helpful is the granularity of the research shows the key drivers of each of these "quality performance indicators" (QPI) and the relative weight of each. This means sites and their research partners understand exactly what should be addressed first to improve performance.

Clinical research performance analytics – the rigorous measurement of service quality through predictive modeling – provides clinical researchers with the ability to break the decades long logjam in study performance by isolating and measuring the key drivers of clinical trials. Those key drivers differ from the perspective of each primary stakeholder – patients, sites, sponsors, and CROs. Understanding them is the first step to addressing and reconciling efforts so all are optimally aligned.

Background

What We're Doing Isn't Working

The first challenge with applying predictive modeling research to clinical research performance is accepting that more data is needed. It's needed for two reasons: 1) what we've been doing isn't working; and 2) it isn't working because industry isn't collecting the data needed to know what to fix first and how to fix it. Let's address the former issue first as the latter is only worth your time because if the desperate nature of the situation.

Good luck finding someone familiar with the pharmaceutical industry to disagree with the premise that clinical research efforts continue to underperform. After almost two decades of steadily rising e-clinical investments and skyrocketing development costs (Chart 1), clinical trial quality as measured by on-time, on-budget performance there's no improvement. In fact, as measured by Tufts University, it has actually decreased slightly.

So how does more data solve the problem? More data is required because the industry currently doesn't routinely or rigorously gather data on the root-cause factors driving what is

measured. Virtually every KPI for every sponsor, CRO, or trial is a measurement of time or quantity and not the underlying causes of that data. What underlies it all is service quality. A clinical trial is a service supported by processes and systems.

Measuring Service Quality

"Clinical trials are a $71 billion industry that offers services critical to the business success of their sponsors and the health and welfare of patients. Despite this importance, there are no widely accepted, scientifically validated measures to track the quality of clinical trials."[1]

Contrary to popular perception, service quality can be rigorously measured. There's even a well-established validated instrument, ServQual, that over years of use has identified the key components and the percent to which each contributes to overall quality: Reliability (32%), Responsiveness (22%), Assurance (19%), Empathy (16%), and Tangibles (11%).

By applying these principles within a predictive modeling methodology in the clinical research environment, the most important items to each study stakeholder can be identified and measured. As importantly, their improvement can be prioritized and impact on operational metrics tracked.

Study Methodology

Because of the above, ACRP and CRO Analytics collaborated to undertake the first ever assessment of clinical trial service quality from the perspective of investigative sites using a predictive modeling methodology. Two questions were at the core of the research:

1. What drives clinical trial performance from the site's perspective?
2. How well are site research partners performing on those drivers?

After using a series of focus groups and interviews the identify the universe of potentially critical items from the perspective of sites, an online survey was conducted using the ACRP data base of clinical site personnel. 273 responses (more than the amount needed for the applied statistical analyses) were received. Respondents were evenly split between those contracting with sponsors and CROs. They constituted a representative sample of study phases, therapeutic areas, study size, responsibilities, and regions. Respondents skewed heavily toward being ACRP certified which can be interpreted as a representing the views of a knowledgeable cohort.

Key Findings

Clinical Trial Performance Drivers as Reported by Investigative Sites (Chart 2)

What these findings show is that the meaningfulness or *impact of communication and the protocol* are the most significant predictors of a high quality clinical trial experience from the perspective of investigative sites. Put differently, data collected from site personnel indicate that improving the performance of the sub-drivers of these two functions results in the most improvement per dollar (or other measurable type of effort) in overall trial quality. The *only other functional areas* with positive regression co-efficients were contract/budgeting, technology, and monitors. To put these in context, a dollar invested in communication (.29) will have three times the impact on overall performance than invested in monitors (.10).

Overall Industry Performance on Clinical Trial Performance Drivers as Reported by Investigative Sites (Chart 3)

So how well is the industry doing on what matters most to sites? Our research showed contracting budgeting to be the lowest scoring area at 6.6. It's important to remember that this incorporates the sites view not just of how much they are paid but also related processes and systems. The highest scoring area was the protocol at 7.7 with the remaining areas falling below that. Communication, the most important area scored a 7.2 while technology and monitors scoring 7.1 and 7.0 respectively.

Sponsor vs CRO Performance on Clinical Trial Performance Drivers as Reported by Investigative Sites (Chart 4)

The differentiation between sponsor and CRO scores on the most critical items, while perhaps not unexpected, was clear and consistent. On average, sponsors scored .5 higher. Notably, the biggest differential was in the most important area, communication. Sponsors scored a 7.8 (the best they did in any category) while CROs came in at 6.6. The two groups scored closest in technology (7.3 vs 6.9).

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CHART 1: Two Decades of Skyrocketing Development Costs, Rising E-Clinical Spending, and No Performance Improvement

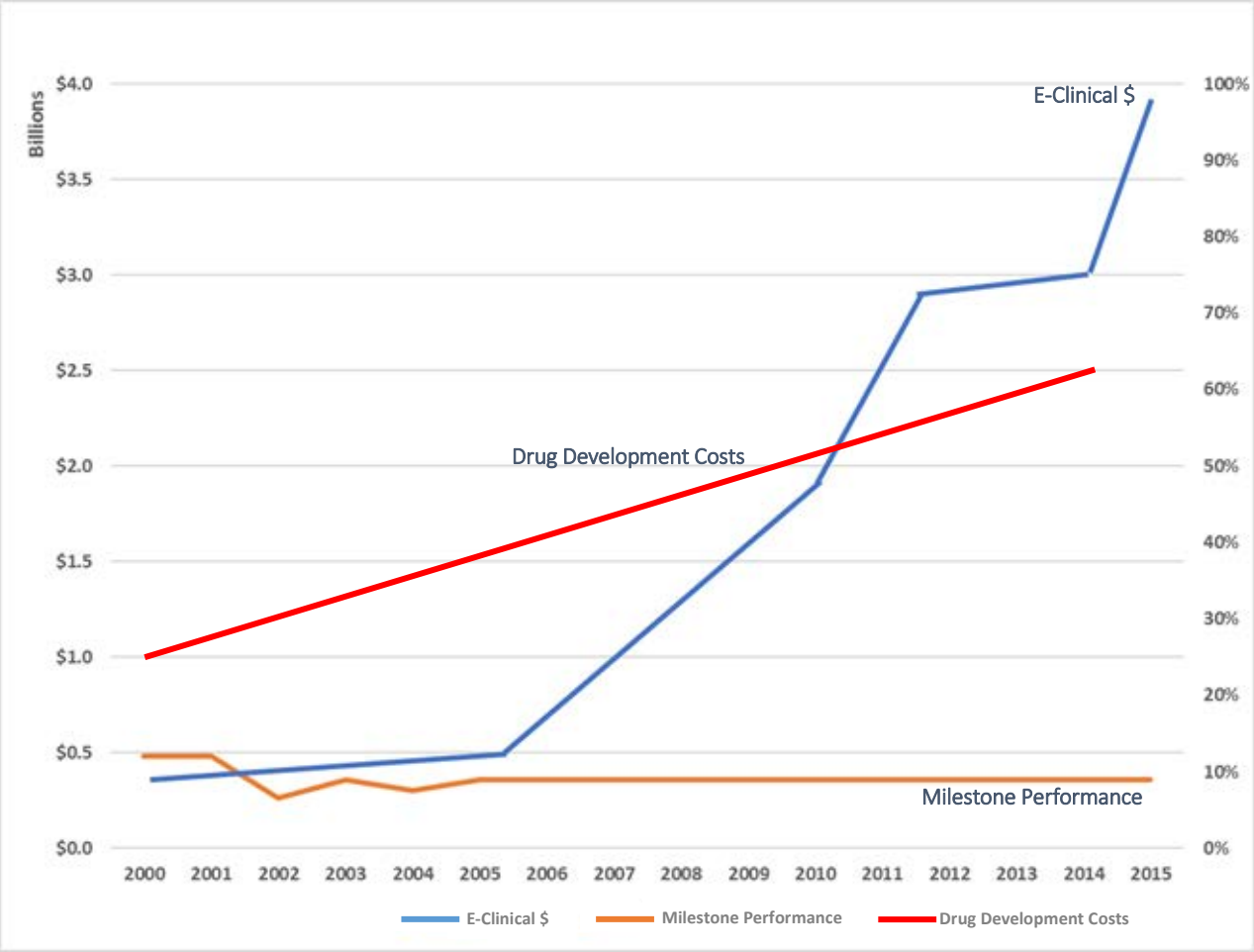

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CHART 2: Clinical Trial Performance Drivers as Reported by Investigative Sites

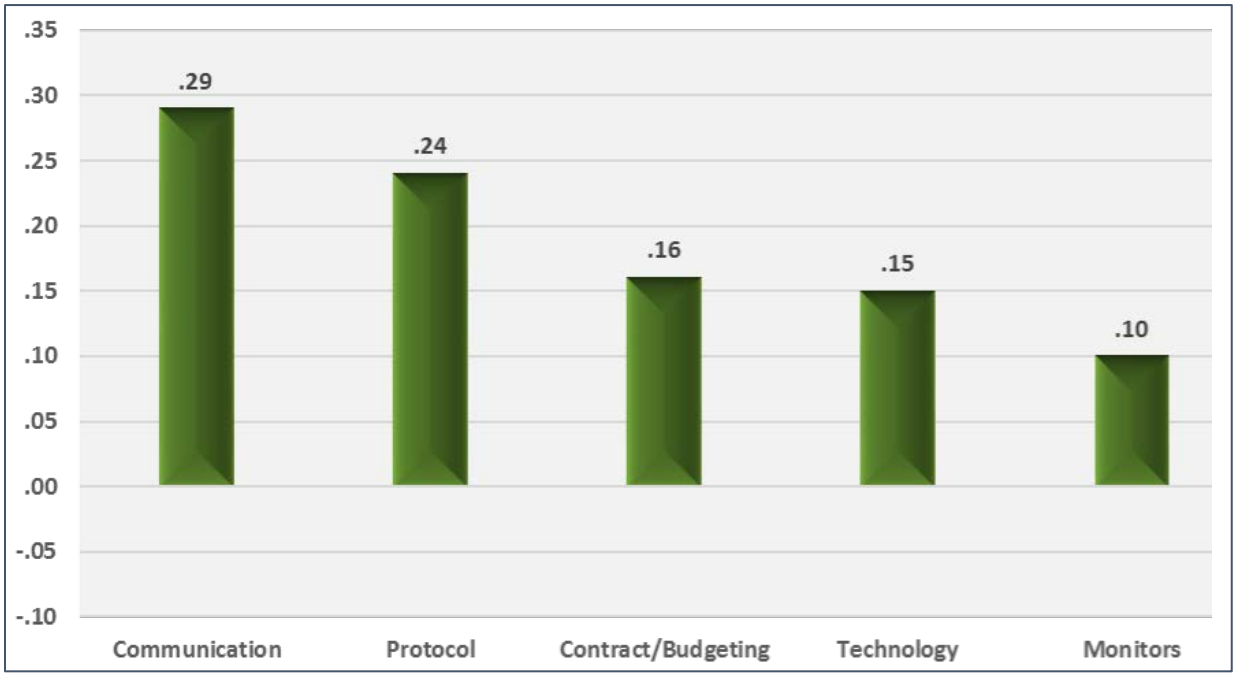

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CHART 3: Overall Industry Performance on Clinical Trial Performance Drivers as Reported by Investigative Sites

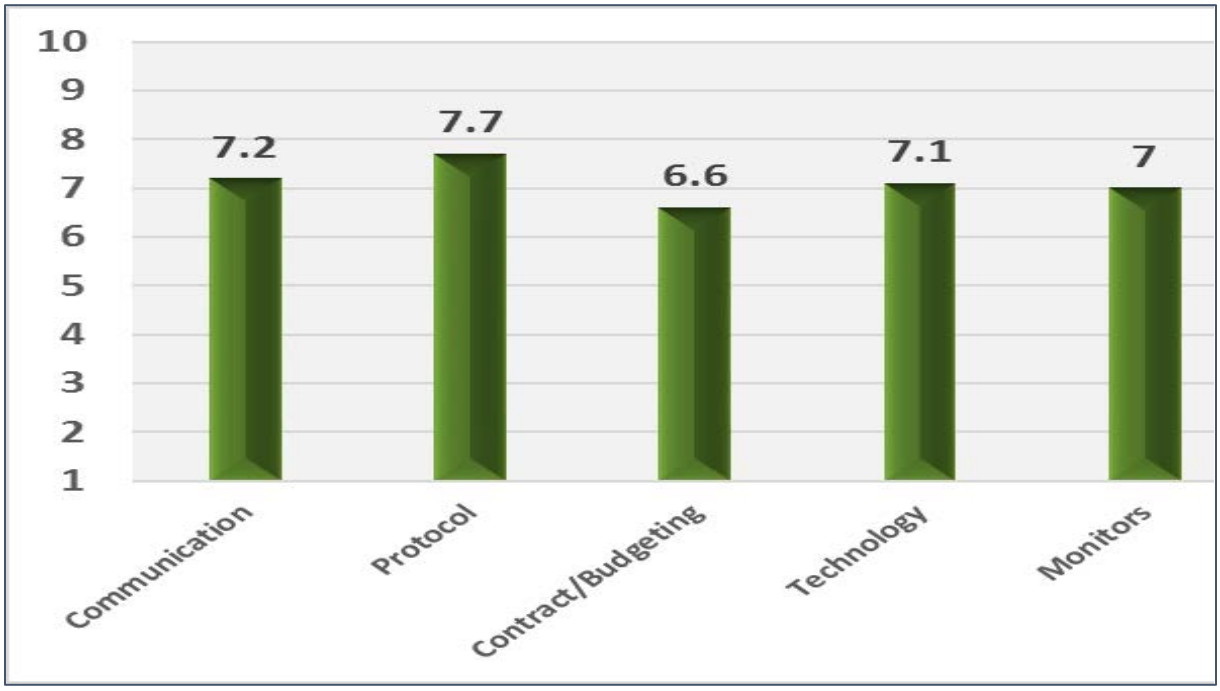

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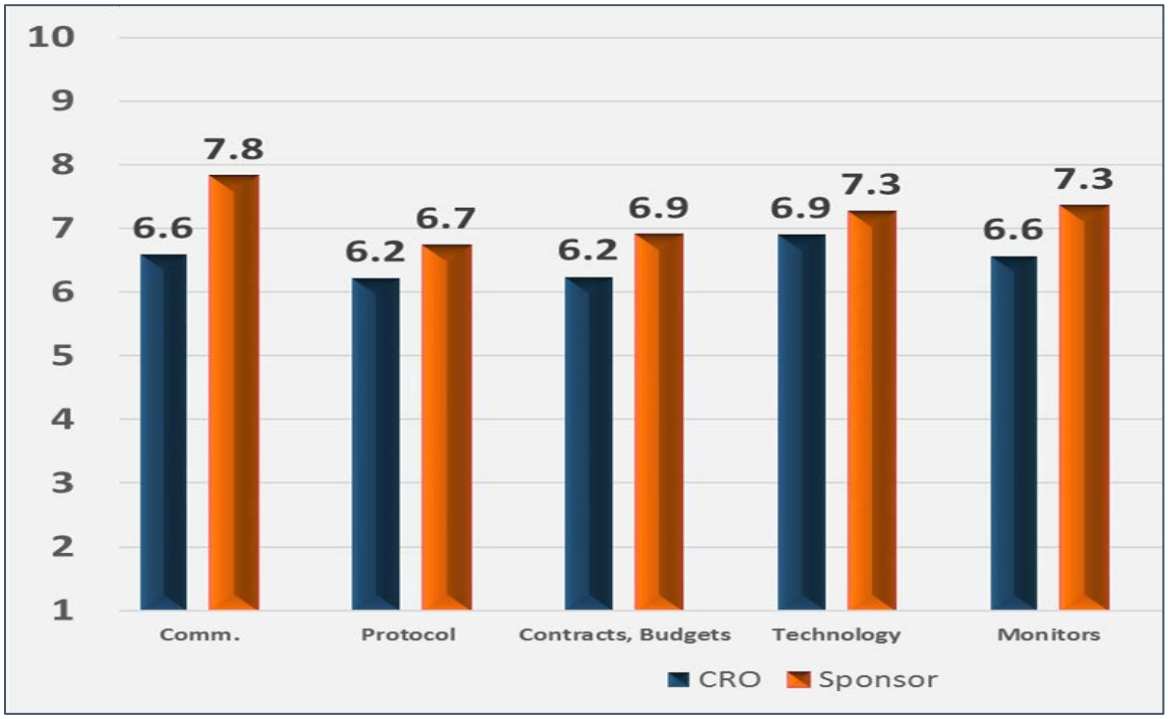
CHART 4: Sponsor vs CRO Performance on Clinical Trial Performance Drivers as Reported by Investigative Sites



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